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| 10/076,785      | 02/15/2002  | Saverio Carl Falco   | BB1336 USCNT        | 4051             |

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EXAMINER

KERR, KATHLEEN M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/076,785

**Applicant(s)**

FALCO ET AL.

**Examiner**

Kathleen M. Kerr

**Art Unit**

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 31-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Application Status***

1. In response to the previous Office action, a non-final rejection (mailed on March 10, 2004), Applicants filed a response and amendment received on June 17, 2004, August 5, 2004 and January 24, 2005. Said amendment amended Claims 31-36, 38, 40, and 42-43. Thus, Claims 31-43 are pending in the instant Office action and will be examined herein.

### ***Priority***

2. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application No. 60/119,599 filed on February 10, 1999 and for the U.S. non-provisional Application No. 09/501,423 filed on February 9, 2000.

As previously noted, SEQ ID NOs:23/24 (full length sequences) are not taught by the provisional application.

The Examiner notes that Applicant has requested a change in the priority claim under 35 U.S.C. § 120 from a continuation, as requested in the preliminary amendment filed on February 15, 2002, to a continuation-in-part, as requested in the amendment to the first paragraph of the specification filed on June 17, 2004.

### ***Withdrawn - Objections to the Specification***

3. Previous objection to the specification because the title is not descriptive is withdrawn by virtue of Applicant's amendment to the title.

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4. Previous objection to the specification for being unclear as to the nature of subclasses of cysteine proteases described therein is withdrawn by virtue of Applicant's amendment deleting the numbering system used.

***Maintained - Objections to the Specification***

5. Previous objection to the amendment filed February 15, 2002 (the filing date of the instant application) is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that the newly filed declaration is sufficient to render the preliminary amendment filed on February 15, 2002 part of the original disclosure. The Examiner disagrees. The substitute declaration filed on June 17, 2004 notes a preliminary amendment filed on "February 12, 2002" (emphasis added) which is 3 days before the filing date of the instant application. Thus, the declaration is defective and cannot be entered to overcome the instant objection.

The Examiner notes that (a) with a proper, new declaration referring to the amendment filed on February 15, 2002 and (b) with the changing of the priority claim under 35 U.S.C. § 120 from a continuation to a continuation-in-part, as filed as part of the first paragraph of the specification amended on June 17, 2004, the subject matter previously objected to will no longer be considered new matter. However, said subject matter will *not* be granted the effective filing date of February 9, 2000 (the CIP parent) for the following reasons:

"The added material which is not supported by the original disclosure is as follows:

- a) ...
- b) All amendments to the sequences iterated in the specification (but not the claims) since these changes alter the definition of the SEQ ID NOs (for example, on page 2, line 13, SEQ ID NO:8 would now be identified as a calpain 94 polypeptide wherein the originally filed document it was not).

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The Examiner has carefully considered Applicants' explanation for the amendments and how it is believed that they are supported in the specification as originally filed. However, the Examiner disagrees that such amendments were supported in the application as originally filed.

With respect to item (i) in each case, the fact that the original filing describes rice sequences as 7 and 8 (which are contradictorily corn sequences in the sequence listing as originally filed) merely indicates an inconsistency and does not indicate sequences 13 and 14 as the rightful sequences in that position in the Table 1, for example, particularly because 13 and 14 are *not* the only rice sequences disclosed. With respect to item (ii), it is clear that Table 6 describes rr1.pk084.j16 as being related to a cysteine protease 1; however, rr1.pk084.j16 is not clearly identified as SEQ ID NO:13 since rr1.pk084.j16 is disclosed as SEQ ID NO:7 in Table 1 as originally filed. While the Examiner does not disagree that SEQ ID NO:7 could not be mistaken for a cysteine protease by one of skill in the art upon an in-depth investigation into sequence homologies, the % identity error referred to in item (iii) is not **readily apparent** in the original disclosure. The standard for new matter is found in M.P.E.P. § 608.04(a):

“Matter not in the original specification, claims, or drawings is usually new matter. Depending on circumstances such as the adequacy of the original disclosure, the addition of inherent characteristics such as chemical or physical properties, a new structural formula or a new use may be new matter.”

While the Examiner agrees that these were probably oversight-type errors on the part of Applicants, which does not change the fact that SEQ ID NO:13 was not identified as a cysteine protease 1 gene, for example, in the original disclosure.”

***Withdrawn - Claim Rejections - 35 U.S.C. § 112***

6. Previous rejection of Claims 31-43 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “compared to one of SEQ ID NO:24” is withdrawn by virtue of Applicant's amendment.
7. Previous rejection of Claims 38, 40 and 42-43 under 35 U.S.C. § 112, second paragraph, as being indefinite for a recombinant DNA construct is withdrawn by virtue of Applicant's amendment requiring a “chimeric gene”. The specification describes a chimeric gene on page 11 as a gene together with a regulatory sequence that are not normally found in nature together.

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Thus, while the Examiner requested “heterologous” in the claim, Applicant’s insertion of “chimeric gene” encompasses the same scope.

***Maintained - Claim Rejections - 35 U.S.C. § 112***

8. Previous rejection of Claims 31-34 and 37-43 under 35 U.S.C. § 112, first paragraph, scope of enablement, is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that the specification discloses a representative number of species within the claimed genus. By virtue of the definite structural breadth and required enzymatic function of the encoded polypeptide, the instant claim have adequate written description.

Applicant argues that, by virtue of the alignment of Gi:2511691 provided showing conserved residues, Applicant is entitled to the breadth of 80% identity since the gi sequence only has 75% sequence identity. The Examiner disagrees. Only 15 residues are described as conserved “in all cysteine proteases” as evidenced by Karrer *et al.* and are conserved in SEQ ID NO:24. No multiple alignment is appended for the Examiner; however, taking this number of 15 residues out of 366 of the total length of 366 of SEQ ID NO:24, 96% percent of the protein can vary as still maintain the conserved residues of “all cysteine proteases”. Thus, a breadth of greater than 96% is not enabled.

9. Previous rejection of Claims 31-43 under 35 U.S.C. § 112, first paragraph, new matter, is maintained in part. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that the supplemental declaration and the changing to CIP status renders the rejection moot. As noted above, the declaration is defective

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and cannot be used to overcome the instant rejection. An effective substitute declaration will overcome the instant rejection.

The rejection of Claim 38 for the word “recombinant” is obviated by virtue of Applicant’s amendment; the rejection for the description of SEQ ID NO:24 as a cysteine protease is maintained.

#### ***Closest Prior Art***

10. As previously noted, the Examiner notes the following as being the closest prior art to the structure of the pending product claims:

- a) Becket *et al.* (see IDS) teach a gene encoding a cysteine protease from *Phaseolus vulgaris* that encodes a protein that is 78% identical (87% similar) to SEQ ID NO:24. Thus, Claims 31-43 are considered free of the prior art. The Examiner also notes that while no particular utility for the claimed invention is described in the specification, utility of cysteine proteases is well-known in the art for use in protein degradation, such as in laundry detergents.

#### ***Other Noteworthy Art***

11. As previously noted, the following are citations of related prior art that do not read on the pending claims for the reasons noted:

- a) Nong *et al.* (cDNA cloning for a putative cysteine proteinase from developing seeds of soybean. *Biochimica et Biophysica Acta* (1995) 1261:435-438) teach a cysteine proteinase from soybean whose amino acid sequence is about 40% identical to SEQ ID NO:24 (see attached alignment). It is not uncommon for two putative cysteine proteinases in the same plant to be this dissimilar (see Becker *et al.* –IDS –with sequences only 32% identical and Domoto *et al.* – IDS –with sequences only 42% identical).
- b) Asano *et al.* (Characterization of novel cysteine proteases from germinating cotyledons of soybean [*Glycine max* (L.) Merrill]. *Journal of Biochemistry* (1999) 126(2):296-301) teach two cysteine proteases purified from soybean of 26,178 and 26,429 Da; no protein *sequences* are disclosed. The sizes of these mature proteins are consistent with neither the protein of Nong *et al.* (mature protein postulated as 26,355 Da) nor SEQ ID NO:24 (mature form not postulated).

***Summary of Pending Issues***

12. The following is a summary of the issues pending in the instant application:
- a) The amendment filed February 15, 2002 (the filing date of the instant application) stands objected to as new matter.
  - b) Claims 31-34 and 37-43 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.
  - c) Claims 31-43 stand rejected under 35 U.S.C. § 112, first paragraph, new matter.

***Conclusion***

13. Claims 31-43 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M. Kerr whose telephone number is (571) 272-0931.

The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr  
Primary Examiner  
Art Unit 1652

April 29, 2005